### REMARKS

Applicant wishes to thank the Examiner for the careful consideration given to this application. Upon entry, claims 20, 21, and 29 will be pending in this application. Claims 8-18, 22-28, 30 and 31 are canceled. Applicant expressly reserves the right to pursue claims incorporating the subject matter of claims 8-18, 22-28, 30 and 31 in one or more continuation or divisional applications. Claim 29 has been amended to incorporate the subject matter of allowed claim 31. No new matter has been added.

#### Allowed Claims

On the Office Action Summary page of the outstanding Office Action, the Examiner indicated that claims 20, 21, and 31 were allowed. As claim 31 is dependent upon independent claim 29, Applicant has amended independent claim 29 to include the subject matter of claim 31. All other pending and withdrawn claims have been canceled. Accordingly, Applicant respectfully asserts that the remaining claims 20, 21, and 29 are in condition for final allowance and respectfully requests notice to such effect.

## Claim Objections

Claims 27 and 28 were objected to for containing informalities. Claims 27 and 28 have been canceled rendering the Examiner's objection moot.

### 35 U.S.C. § 112

Claims 22-28 were rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Claims 22-28 have been canceled rendering the Examiner's rejection moot.

Claims 22-25 and 27-30 were rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking written description in the specification as filed. Claims 22-25 and 27, 28, and 30 were canceled rendering the Examiner's rejection moot.

With regard to independent claim 29, Applicant initially notes that the Examiner has incorrectly characterized Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559 which states at page 1567:

"An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by

Attorney Docket No. 125192.00501

structure, formula, chemical name, <u>or physical properties</u>," not a mere wish or plan for obtaining the claimed chemical invention." *quoting* Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed.Cir.1993) (emphasis added).

Therefore, contrary to the Examiner's assertion, the U.S. Court of Appeals, Federal Circuit has held that the written description requirement is satisfied by precisely describing the physical properties of a microorganism. Applicant respectfully asserts that independent claim 29 precisely describes the physical properties of Applicant's claimed human cell strain thereby satisfying the written description requirement. Nonetheless, solely to facilitate allowance of the pending claims, Applicant has amended independent claim 29 to include Applicant's specific human cell strains recited in allowed claim 31. Accordingly, withdrawal of the Examiner's rejection is respectfully requested.

Claims 22-25 and 27-30 were rejected under 35 U.S.C. § 112, first paragraph as allegedly not being enabled by the specification as filed. Claims 22-25 and 27, 28, and 30 were canceled rendering the Examiner's rejection moot.

With regard to independent claim 29, Applicant respectfully disagrees with the Examiner's assessment of Applicant's specification. First, independent claim 29 recites physical properties of a human cell strain that Applicant achieved, see Tables 1-3 and corresponding text. Applicant respectfully asserts, that the skilled artisan could easily determine how a cell line exhibiting such physical attributes can be used, for example, for expressing the Antibody Heavy Chain Protein, as in Example 1 and 4-6, Interleukin 1α Protein, as in Example 2, and jellyfish GFP, as in Example 3. Second, canceled independent claim 22, which the Examiner identifies as "having a product by process type limitation" (see Office Action, pg. 12), recites a "process type limitation" which describes how to make Applicant's claimed human cell strain, thereby providing teaching with regard to how to make Applicant's claimed human cell strain. Therefore, for at least these reasons, Applicant respectfully asserts that independent claim 29 in its previously presented form is fully enabled by the specification as originally filed because the specification teaches how to make and use applicant's claimed human cell strain. Nonetheless, solely to facilitate allowance of the pending claims, Applicant has amended independent claim 29 to include Applicant's specific human cell strains recited in allowed claim 31. Accordingly, withdrawal of the Examiner's rejection is respectfully requested.

### 35 U.S.C. § 102

Claims 22-25 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Pene et al., Oncogene, 21:6587-6597 (2002). Claims 22-25 have been canceled rendering the Examiner's rejection moot.

Claims 22-25 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hata et al., Clin. Exp. Immunol., 94:370-375 (1994). Claims 22-25 have been canceled rendering the Examiner's rejection moot.

Claims 22-24, 27, and 29 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Karpas et al., PNAS, 96:1799-1804 (2001) ("Karpas"). Claims 22-24 and 27 have been canceled rendering the Examiner's rejection moot.

Independent claim 29 has been amended to incorporate the subject matter of claim 31 which was indicated as being allowed. Accordingly, amended independent claim 29 is now in condition for allowance, and withdrawal of the Examiner's rejection of independent claim 29 is respectfully requested.

### 35 U.S.C. § 103

Claims 22-24 and 27-29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Karpas in view of Kawahara et al., Human Antibodies, 9:83-87 (1999) and Tonguzzo et al., Mol. and Cell Biol., 6:703-706 (1986). Claims 22-24 and 27 have been canceled rendering the Examiner's rejection moot.

Independent claim 29 has been amended to incorporate the subject matter of claim 31 which was indicated as being allowed. Accordingly, amended independent claim 29 is now in condition for allowance, and withdrawal of the Examiner's rejection of independent claim 29 is respectfully requested.

# **CONCLUSION**

Applicant believes that no fee is due for this response and amendment; however,iIn the event that an additional fee is required for this response, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-0436.

Applicant believes that this application is in condition for allowance. However, should the Examiner have any questions or comments, or need any additional information from Applicant's attorney, please contact the undersigned attorney at your convenience.

Respectfully submitted,

James M. Singer

Registration No. 45,111

PEPPER HAMILTON LLP One Mellon Center, 50<sup>th</sup> Floor 500 Grant Street Pittsburgh, PA 15219

Phone: (412) 454-5000 Fax: (412) 281-0717

Date: June 30, 2009